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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,762	08/26/2003	Daniel J. Burdick	P1365R2C1	7341

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EXAMINER	
NAGUBANDI, LALITHA	
ART UNIT	**PAPER NUMBER**
1621	

MAIL DATE	DELIVERY MODE
07/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,762	BURDICK ET AL.	
	Examiner	Art Unit	
	Lalitha Nagubandi	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Office Action

Status of Claims

Claims 1-18 are pending. Claims 1-18 are considered for examination in this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, page 2, lines 11-15, and page 4, line 16, the use of group ' $S(O)_s$' is unclear. Claim 1 and further the claims dependent on claim 1 are therefore rendered indefinite.

Claim Objections

Claim1 is objected to because of the following informalities: The word ' substitute' is misspelled at several places in claim 1. Appropriate correction is required. It is appreciated if applicant can rectify any typographical errors further noticed during the amendment in all the dependent claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 9 applicant has used the terms both 'treatment or ameliorating', which is not quite clear. It is suggested that applicant makes it clear for the record and appropriate correction is made in the next office action.

Claim Rejections - 35 USC § 112

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands factors* (MPEP 2164.01 (a)) as the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (Board Apls. 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the existence of working examples; and (8) the quantity of experimentation necessary. Some of the *Wands factors* have been considered with regard to the instant application, with the most relevant factors discussed below.

Nature of the Invention

All of the rejected claims are drawn to an invention, which pertains to a method of treating or ameliorating a disease or disorder in a mammal mediated through the CD11/CD18 family of adhesion receptors comprising administering a pharmacologically effective amount of a compound embodied as in claim 1.

Breadth of the Claims

The complex nature of the claims is greatly exacerbated by breadth of the claims. Claims 9-12 encompass a method of treating or ameliorating a disease or disorder in a mammal mediated by binding interaction of LFA-1 and ICAM-1, does not clearly state whether it is (i) treating or ameliorating a disease in a mammal mediated through the CD11/CD18 family of adhesion receptors, administering effective amount of the embodied compound(s). (ii) treating or ameliorating a disorder in a mammal mediated through the CD11/CD18 family of adhesion receptors, administering effective amount of the embodied compound(s) is rather unclear.

Guidance of the Specification/ Working Examples

There is no guidance given by the specification as to which type of treating measures has to be used to achieve the best results.

All of the guidance provided by the specification is directed towards the assay studies directed towards, Example 1: Preparation and purification of full length LFA-1, Example 2: 293 cells ICAM-1-immunoadhesin, Example 3: ICAM:LFA-1 Receptor Binding Assay, Example 4: Human T-cell Adhesion Assay, Example 5: T-cell proliferation assay (co-stimulation assay), Example 6: In vitro Mixed Lymphocyte Culture Model, Example 7: Compound Synthesis and Activity.

All of the working examples provided by the specification are directed towards the assay studies rather than the comparative aspects of a known compound is not enabled or if it is enabled, it is unclear to the examiner. The table, provided by the applicant on page 160 of the specification is in no way showing the effective amount of a compound where one can indicate that a particular compound can treat a disease as embodied in the instant invention?

Predictability of the Art

The instant application is directed to a method of treating or ameliorating a disease or disorder in a mammal mediated by binding interaction of CD11/CD18 family of adhesion receptors comprising administering a pharmacologically effective amount of a compound according to claim 9, is rather broad and unclear. In the instant case, the compound is highly unpredictable as far as the treatment or ameliorative aspect, since one skilled in the art cannot fully describe, visualize or recognize the identity of the mode of action of the compound by structure, formula or structure-activity relationship. Specially when it has to be a combination of structure, function and pathological role of leukocyte function-associated antigen-1 (LFA-1) which is a heterodimeric protein consisting of two subunits. T-Cell activation can be suppressed by blocking ICAM -1/LFA-1 interaction in autoimmune diseases and organ transplantation. Hence, in the absence of fully recognizining the identity of the above said properties, one of

skill in the art would be unable to fully predict which compound would have the claimed properties described.

Hence, a method of treating or ameliorating a disease or disorder in a mammal mediated through the CD11/Cd18 family of adhesion receptors comprising administering a pharmacologically effective amount of a compound has not been considered enabled by the instant specification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eyler, Yvonne can be reached on 571 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lalitha Nagubandi
Patent Examiner
Technology Center 1600

July 3rd, 2007.

Samuel A Barts

Primary Patent Examiner

Technology Center 1600